UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/508,254	10/02/00	CHARETTE M	00960-558

HM12/0705

IVOR R ELRIFI
MINTZ LEVIN COHN FERRIS GLOVSKY & POPEO
ONE FINANCIAL CENTER
BOSTON MA 02111

EXAMINER	
HAYES, R	
ART UNIT	**PAPER NUMBER**
1647	5

DATE MAILED: 07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/508,254	CHARETTE ET AL.	
	Examiner	Art Unit	
	Robert C. Hayes	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Peri d for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 October 2000* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-29* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 11-23 and 28-29, in part, drawn to a method for promoting growth of mammalian neural cells and a pharmaceutical preparation comprising a GDNF/NGF neurotrophic factor and an OP/BMP morphogen.

Group II, claim(s) 2, drawn to a method for inhibiting the degeneration of mammalian neural cells.

Group III, claim(s) 3 and 5-23, in part, drawn to a method for treating a mammalian subject afflicted with damage or injury to neural cells comprising contacting neural cells with a preparation comprising a morphogen and a GDNF/NGF neurotrophic factor.

Group IV, claim(s) 4-23, in part, drawn to a method for treating a mammalian subject at imminent risk of damage or injury to neural cells comprising contacting neural cells with a preparation comprising a GDNF/NGF neurotrophic factor and an OP/BMP morphogen.

Group V, claim(s) 24, drawn to a method for promoting the survival or growth of mammalian cells, wherein said cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor.

Group VI, claim(s) 25, drawn to a method for inhibiting the death or degeneration of mammalian cells, wherein said cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor.

Group VII, claim(s) 26, drawn to a method for treating a mammalian subject afflicted with damage or injury to cells, wherein said cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor.

Group VIII, claim(s) 27, drawn to a method for treating a mammalian subject at imminent risk of damage or injury to cells, wherein said cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor.

2. The inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the technical feature of a pharmaceutical composition comprising a GDNF/NGF neurotrophic factor and an OP/BMP morphogen and a method for promoting growth of mammalian neural cells comprising contacting the neural cells with the composition, which is not required by the other methods of Groups II-VIII

Group II recites the technical feature of inhibition of the degeneration of mammalian neural cells, which is not required by the other methods of Groups I and III-VIII.

Group III recites the technical feature of treatment of a mammalian subject afflicted with damage or injury to neural cells, which is not required by the other methods of Groups I-II and IV-VIII.

Group IV recites the technical feature of treatment of a mammalian subject at imminent risk of damage or injury to neural cells, which is not required by the other methods of Groups I-III and V-VIII.

Group V recites the technical feature of promotion of the survival or growth of mammalian cells, wherein the cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor, which is not required by the other methods of Groups I-IV and VI-VIII.

Group VI recites the technical feature of inhibition of the death or degeneration of mammalian cells, wherein the cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor, which is not required by the other methods of Groups I-V and VII-VIII.

Group VII recites the technical feature of treatment of a mammalian subject afflicted with damage or injury to cells, wherein the cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor, which is not required by the other methods of Groups I-VI and VIII.

Group VIII recites the technical feature of treatment of a mammalian subject at imminent risk of damage or injury to cells, wherein the cells express an OP/BMP-activated serine/threonine kinase receptor and a GDNF/NGF-activated tyrosine kinase receptor, which is not required by the other methods of Groups I-VII.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of damage or injury are as follows:

a. mechanical trauma

b. chemical trauma

c. ischemia of a tissue

d. neuropathic disease

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-2 and 24-29.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (a) is mechanical trauma tissue damage or injury. This special technical feature is not shared by any of the other species.

5. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of neuropathic disease are as follows:

e. Parkinson's disease

f. Huntington's disease

g. Amyotrophic Lateral Sclerosis

h. Alzheimer's disease

i. epilepsy

j. progressive muscular atrophy

k. Charcot-Marie-Tooth disease

l. palsy

m. dementia

n. Shy-Drager disease

o. Wernicke-Korsakoff syndrome

p. Hallervorden-Spatz disease

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-2 and 24-29.

6. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (e) is the neuropathic disease of Parkinson's disease, which causes damage or injury to neural cells. This special technical feature is not shared by any of the other species.

7. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of neural cells are as follows:

q. central nervous system cells

r. peripheral nervous system cells

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

8. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (q) is central nervous system cells. This special technical feature is not shared by any of the other species.

9. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of OP/BMP morphogen C terminal six- or seven cysteine domain of a mammalian protein are as follows:

s. OP-1

t. OP-2

u. OP-3

v. BMP2

w. BMP3

x. BMP4

y. BMP5

z. BMP6

aa. BMP9

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

10. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (s) is the C-terminal six- or seven-cysteine domain of OP-1. This special technical feature is not shared by any of the other species.

11. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species of GDNF/NGF neurotrophic factor that comprises a functional form of a protein are as follows:

bb. GDNF

cc. NGF

dd. BDNF

ee. NT-3

ff. NT-4

gg. NT-5

hh. NT-6

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

12. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The special technical feature of (bb) is the functional form of GDNF that comprises the GDNF/NGF neurotrophic factor. This special technical feature is not shared by any of the other species.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

If Applicant elects Group I-VIII, one species from the neural cell group, one species from the OP/BMP morphogen mammalian protein group, and one species from the GDNF/NGF functional form group must be chosen to be considered fully responsive.

If Applicant elects Group II or III, one species from the cell damage/injury group and one species from the neuropathic disease group must also be chosen to be considered fully responsive.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert C. Hayes whose telephone number is (703) 305-3132.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

BEB
Art Unit 1647
July 2, 2001

Yvonne Eyler

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600